DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 5, 2014

Q Core Medical Limited
C/O Ms. Rhona Shanker
Director, Regulatory Consulting
12154 Darnestown Road, #236
Gaithersburg, MD 20878

Re: K141834
Trade/Device Name: Q Core Administration Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Administration Set
Regulatory Class: II
Product Code: FPA
Dated: July 7, 2014
Received: July 7, 2014

Dear Ms. Shanker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K141834

Device Name

Administration Set

Indications for Use *(Describe)*

The dedicated Q Core administration sets for the Sapphire pump are intended for single-patient use and single-use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Mary E. Brooks -A
2014.08.05 13:52:51 -04'00'

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**510(k) Summary**

| | |
|---|---|
| Owner/Submitter | Q Core Medical Ltd.<br>29 Yad Haruzim St.<br>Netanya 4250529<br>ISRAEL<br>Ph: +972-73-2388888<br>Fax: +972-73-2388800 |
| Contact Person | Rhona Shanker<br>FDA Regulatory Consultant to Q Core Medical Ltd<br>Ph: 301251-9570<br>Fax: 301-251-9571 |
| Trade Name | Q Core Administration Set |
| Common Name | Administration Set |
| Classification Name | Intravascular administration set 21 CFR 880.5440<br>Product Code:<br>FPA - Administration Sets<br>Class II |
| Predicate Device Administration Sets | Q Core Administration Sets cleared under K123049<br>Bodyguard Infusion System sets with back check valve cleared under K031749 |

**Device Description**

The dedicated Q Core Administration Sets for the Sapphire infusion pump are provided sterile and are for single-use and single-patient use only. Components from the previously cleared administration sets were used to make a set with new configuration, all within the parameters (e.g. length, diameters, materials) of the sets cleared with the Sapphire Infusion Pump. This new configuration is substantially equivalent to the administration sets that were cleared under K123049, having identical indications for use and technological characteristics. In addition, this set includes a pressure activated back check valve ("PAV") that has the same cracking pressure as the back check valve that was cleared with administration sets under K031749 (Bodyguard

Infusion System). The PAV valve has been added to make it consistent with other sets on the market.

**Indications for Use**

The dedicated Q Core administration sets for the Sapphire pump are intended for single-patient use and single-use only.

These are the same indications for use as the predicate Administration Sets cleared under K123049.

**Technological Characteristics**

The proposed Q Core Administration Set configuration to be used with the Sapphire Infusion Pump is substantially equivalent to the primary predicate devices (K123049) in the following respects:

1. All sets are dedicated for use with Q Core infusion pumps.
2. All sets can be used only by or under the order of a licensed medical practitioner.
3. All sets consist of standard, conventional components such as Luer locks, PVC tubing, Y-connector, tubing clamp.
4. All sets use materials with the same characteristics (biocompatible, non-DEHP, latex free).
5. All sets have a cassette with an Anti-Free Flow Valve [AFFV] and other means to protect against free flow. The new set includes an additional means to protect against free flow, which is the inclusion of a pressure activated back check valve (PAV) that has the same cracking pressure as the back check valve that was cleared under K031749 (Bodyguard Infusion System)
6. All sets are provided sterile, non-pyrogenic, intended for single patient use and single use.
7. All sets are intended for either hospital or home use.

**Pre-Clinical Testing**

Preclinical testing included in the submission to demonstrate that the new administration set is safe and performs as intended involved the following:

- Visual tests
- Dimensional testing
- Physical requirements
- Flow accuracy

**Conclusion**

The new Administration Set having the new configuration and an additional pressure activated back check valve, that is to be used with the Sapphire Infusion Pump, is substantially equivalent to sets cleared under K123049 (primary predicate) with respect to the indications for use, technological characteristics and materials and to K031749 (Bodyguard Infusion System) with respect to the cracking pressure of the back check valve.

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